Response to Restriction Requirement

Restriction to one of the following inventions is required under 35 USC 121:

I. Claims 1, 2, 6(16) and 7(17) are drawn to a method of gene therapy by small fragment homologous replacement, classified in class 514, subclass 44.

II. Claim 3(12) is drawn to a genomic DNA sequence of human cystic fibrosis exon 10, classified in class 536, subclass 23.1.

III. Claim 4(13) is drawn to a transgenic animal, classified in class 800, subclass 3.

IV. Claim 5(14) is drawn to a method of targeted small fragments homologous replacement of provirus of HIV, classified in class 424, subclass 93.6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05(h)). In the instant case the genomic DNA sequence of human cystic fibrosis transmembrane conductance regulator gene exon 10 of invention II could be used as a probe for hybridization assays.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP §806.05(f)). In the instant case, invention I is drawn to a method of gene therapy with small fragment homologous replacement could be used to treat without the production of a transgenic animal of invention III.

Inventions I and IV are drawn to mutually exclusive and independent methods. Invention I is to a method of gene therapy of a disease associated with a mutated DNA fragment in a subject's target cells. Invention IV is to a method for targeted small fragments homologous replacement of provirus HIV. The two methods require separate and distinct protocols. Neither invention I or invention IV is required for implementation of the other invention.

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP §806.05(f)). In the instant case, invention II is drawn to a genomic DNA sequence of human cystic fibrosis transmembrane gene could be used as a probe for hybridization assays.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05(h)). In the instant case the genomic DNA sequence of human cystic fibrosis transmembrane conductance regulator gene exon 10 of invention II could be used as a probe for hybridization assays.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). Inventions III and IV are drawn to mutually exclusive and independent inventions. Invention III is to a cystic fibrosis transgenic mouse model. Invention IV is to a method for targeted small fragment homologous replacement of provirus HIV. The transgenic mouse model requires separate and distinct protocols from that of the small fragment homologous replacement of with provirus HIV. Neither invention III or IV is required for implementation of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicants disagree. However, in order to advance the examination, Applicants elect to prosecute Group I, claims 1, 2, 6 and 7, directed to a method of gene therapy by small fragment homologous replacement. However, in order to provide claims in better condition for examination, Applicants canceled claims 1, 2, 6 and 7 and added new claims 8-16.

Examiner is respectfully requested to enter this Amendment and examine claims 8-16.

Change of Name

Applicant respectfully requests Examiner to note a change of her name which should have been reflected in the file. The Change of Name documents are executed.

SUMMARY

In summary, Applicants elected to prosecute invention of Group I. Applicants cancel claims 1, 2, 6 and 7 and added new claims 8-16 which are believed to be in better condition for examination.

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Respectfully submitted,

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